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**California Department of Public Health**



EDMUND G. BROWN, JR.  
Governor

December 7, 2012

AFL 12-45

**TO:** Primary Care Clinics (PCCs)  
General Acute Care Hospitals (GACHs)  
Acute Psychiatric Hospitals (APHs)  
Skilled Nursing Facilities (SNFs)  
Intermediate Care Facilities (ICFs)  
ICF – Developmentally Disabled facilities (ICF-DDs)  
ICF-DD-Habilitative facilities (ICF-DD-Hs)  
ICF-DD-Nursing facilities (ICF-DD-Ns)  
Correction Treatment Centers (CTCs)  
Chemical Dependency Recovery Hospitals (CDRHs)

**SUBJECT:** Opportunities to Participate in Drug Repository and Distribution Programs (RDPs)

**AUTHORITY:** Senate Bill (SB) 1329 (Statutes of 2012, Chapter 709) – Health & Safety Code (HSC) Sections 150200-150207.

This All Facilities Letter (AFL) serves as notification for changes taking effect January 1, 2013, related to Drug Repository and Distribution Programs (RDPs). This letter additionally touches upon the requirements for those facilities or clinics licensed by the California Department of Public Health (CDPH) that choose to participate in an RDP, whether as donors or as distributors of donated medication. However, as the laws related to participation in an RDP are not enforced by CDPH, facilities and clinics that choose to participate will need to review all of the laws related to RDPs (HSC Sections 150200-150207) to ensure their compliance with the requirements of participation, which are enforced by local health departments and the California Board of Pharmacy (BOP).

### **Background**

In 2006, SB 798 (Statutes of 2005, Chapter 444) enacted law (HSC Sections 150200-150207) creating the process for a county to establish an RDP for the distribution of unused medication to medically indigent patients, authorizing SNFs to donate unused medication and authorizing county pharmacies to distribute the donated medication.

SB 1329 (Statutes of 2012, Chapter 709), amended the process for a county to establish an RDP, added several categories of licensed health care facilities that may

donate medications to an RDP, and allowed both primary care clinic (PCC) pharmacies and PCCs that have BOP licenses to administer and dispense medication (provided their BOP licenses are in good standing) to distribute donated medications. A county that establishes an RDP must notify the BOP within 30 days of establishing the program.

### **CDPH licensed facilities that may donate medications**

Effective January 1, 2013, the following CDPH licensed health care facilities may donate unused medication through a county-established RDP:

- GACHs
- APHs
- SNFs (including SNFs with Special Treatment Programs)
- ICFs
- ICF-DD-Hs
- ICF-DD-Ns
- CTCs
- CDRHs

Donating facilities remain responsible for ensuring their compliance with all CDPH licensing requirements related to pharmaceutical services, including drug distribution, storage and disposal.

### **Drugs or medication that can be donated**

Donated medication/drugs MUST:

- Have been centrally stored while on the donor facility's premises.
- Have been delivered from the dispensing pharmacy, wholesaler or manufacturer directly to the donor facility. (Note: centrally stored medication that originated from a patient or resident cannot be donated.)
- Not be a controlled substance (e.g., drugs listed under Schedules II, III or IV of the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970).
- Not be adulterated, misbranded, or stored under conditions contrary to standards set by the United States Pharmacopoeia (USP) or the product manufacturer.
- Not have been in the possession of a patient or any individual member of the public.
- Have been under the control of either a licensed health care professional or a staff member of the facility who has completed, at a minimum, the training requirements specified in HSC Section 1569.69.
- Be in unopened, tamper-evident packaging or modified unit dose containers that meet USP standards with lot numbers and expiration dates affixed.
- Be unexpired.
- Have been otherwise scheduled for destruction by the facility or another appropriate entity.

### **Which PCCs are allowed to distribute donated medications?**

When RDPs were originally authorized in 2006, only county-owned or county-contracted pharmacies were allowed to distribute the donated medications. SB 1329 expands this eligibility to PCCs, as long as they have either a BOP licensed pharmacy, or are BOP licensed to administer and dispense medications, and provided they meet the requirements of “Participating Entities.”

### **Requirements of “Participating Entities”**

To qualify as a “participating entity” and become able to distribute donated medication, PCCs must:

- Provide written notification of intent to participate in an RDP to the county health department and BOP [Note: A PCC cannot participate until it receives documentation from its county health department that notification of intent has been received.]
- Provide quarterly disclosure to the county health department of the sources (including name and location) of all the donated medication it has received.
- Disclose to the county health department the name of the licensed physician and/or pharmacist who shall be accountable to the BOP for the clinic’s RDP participation.
- Have a pharmacist, or designated physician, available and able to determine that donated medications meet all the requirements of “medications allowed for donation” before accepting or dispensing them.
- Have a pharmacist, or the designated physician, adhere to standard pharmacy practices, as required by state and federal law, when dispensing medications, following the same procedural drug pedigree requirements for donated drugs as he or she would for drugs purchased from a wholesaler or drug manufacturer.
- Comply with the county RDP participation protocols for:
  - Determining patient eligibility for donated medication,
  - Providing the medication at no cost,
  - Adhering to the formulary of appropriate medications,
  - Ensuring proper safety and management of donated medications, and
  - Ensuring the privacy of individuals for whom the medication was originally prescribed.

### **What are the liability issues?**

Donating facilities and participating entities shall not be subject to criminal or civil liability for injury caused when donating, accepting, or dispensing prescription drugs through an RDP except as a result of noncompliance with the laws governing RDPs, bad faith or gross negligence.

The information in this AFL provides only a summary of SB 1329’s changes to Health and Safety Code; additional requirements are provided in the statutory language. Donating facilities and participating entity PCCs are responsible to ensure their own compliance with all of the requirements defined in HSC 150200-150207, their county’s

applicable RDP participation protocols, and the CDPH licensing requirements related to handling, distributing, disposing and/or otherwise managing drugs, medications and/or pharmaceuticals for their licensure category. CDPH's failure to expressly notify facilities of legislative changes does not relieve facilities of their responsibility for following all laws and for being aware of all legislative changes.

Facilities that wish to participate in an RDP should refer to the full text of HSC Sections 150200-150207 to ensure compliance, which is available online to view or print at:

<http://www.leginfo.ca.gov/cgi-bin/displaycode?section=hsc&group=150001-151000&file=150200-150207>

To determine whether your county has established an RDP, please contact your local public health official. If you have questions related to compliance with facility or clinic pharmaceutical services licensing requirements as they may relate to participation in an RDP, please contact the L&C Pharmaceutical Consultant Unit at (916)445-8683.

Sincerely,

**Original signed by Debby Rogers**

Debby Rogers, RN, MS, FAEN  
Deputy Director  
Center for Health Care Quality